



## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OW-2002-0011; FRL -9900-75-OW]

### **Proposed Information Collection Request; Comment Request; Laboratory Quality Assurance Evaluation Program for Analysis of *Cryptosporidium* under the Safe Drinking Water Act (Renewal)**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency is planning to submit an information collection request (ICR), “Laboratory Quality Assurance Evaluation Program for Analysis of *Cryptosporidium* under the Safe Drinking Water Act” (EPA ICR No. 2067.05, OMB Control No. 2040-0246) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through January 31, 2014. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

**DATES:** Comments must be submitted on or before [\[insert date 60 days after publication in the Federal Register\]](#).

**ADDRESSES:** Submit your comments, referencing Docket ID No. EPA-HQ-OW-2002-0011, online using [www.regulations.gov](http://www.regulations.gov) (our preferred method), by email to [ow-docket@epa.gov](mailto:ow-docket@epa.gov), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity,

threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

**FOR FURTHER INFORMATION CONTACT:** Carrie Miller, Technical Support Center (TSC), Office of Ground Water and Drinking Water, (MS-140), Environmental Protection Agency, 26 West Martin Luther King Drive, Cincinnati, Ohio 45268; telephone number: 513-569-7919; fax number: 513-569-7191; email address: [miller.carrie@epa.gov](mailto:miller.carrie@epa.gov).

**SUPPLEMENTARY INFORMATION:**

Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at [www.regulations.gov](http://www.regulations.gov) or in person at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit <http://www.epa.gov/dockets>.

Pursuant to section 3506(c)(2)(A) of the Paperwork Reduction Act, EPA is soliciting comments and information to enable it to: (i) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to

OMB for review and approval. At that time, EPA will issue another Federal Register notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

*Abstract:* Under the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR), EPA requires public water systems to use approved laboratories when conducting *Cryptosporidium* monitoring. 40 CFR 141.705(a) provides for approval of *Cryptosporidium* laboratories by “an equivalent” State laboratory certification program (i.e., equivalent to EPA’s Laboratory Quality Assurance Evaluation Program). In the preamble to the LT2ESWTR, as well as several other notices, EPA has described the criteria for approval of laboratories to analyze *Cryptosporidium* samples under the LT2ESWTR. See 74 FR 8529 (February 25, 2009), 71 FR 727 (January 5, 2006) and 67 FR 9731 (March 4, 2002).

Through today’s notice, EPA is inviting comment on refinements to the information collected to support EPA’s Lab QA Program. The procedures for Methods 1622, 1623, and 1623.1 (a revision of Method 1623) have been updated to reflect that the minimum recovery for *Cryptosporidium* in ongoing precision and recovery (OPR) samples is now 33 percent. This minimum recovery is based on an updated data set and should provide a better assessment of laboratory performance than the previous value for the following reasons: 1) the data set is more recent; and 2) the sample size is more than twice as large as the 2009 sample size used to establish the previous value.

State responsibilities for *Cryptosporidium* laboratory approval and oversight will be comparable to their certification responsibilities for the chemistry and microbiology laboratories that they oversee in their current programs (e.g., initial evaluation of laboratory capability; ongoing assessment of the laboratory – including an assessment of Proficiency Test results; and on-site audits at least triennially). Whereas 40 CFR 142.10(b) generally requires the establishment and

maintenance of a laboratory “certification” program for all regulated analytes, State approval programs for *Cryptosporidium* laboratories are optional based on the structure of the LT2ESWTR (40 CFR 141.705(a)).

If a laboratory is located in a State that does not operate a *Cryptosporidium* laboratory certification/accreditation program, that laboratory can still support LT2ESWTR monitoring if the laboratory has been approved by another State’s laboratory certification/accreditation program that: (1) has demonstrated substantial conformity to procedures described in Chapter 7 of “Supplement 2 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water” <http://water.epa.gov/scitech/drinkingwater/labcert/index.cfm#two> and (2) uses auditors that have passed the Technical Support Center’s (TSC) *Cryptosporidium* Laboratory Certification Officers Training Course. PWSs should be aware that their States may establish requirements that are more stringent than EPA’s regulations; State requirements would take precedence.

Consistent with the longstanding laboratory certification program approach, TSC will: (1) train State/Regional Certification Officers (CO) responsible for auditing *Cryptosporidium* laboratories; (2) provide written guidance to State/Regional COs; (3) provide day-to-day technical support to States, Regions, and laboratories; (4) review/assist the Regional programs that oversee State certification/accreditation programs; and (5) maintain a list of links to State websites naming certified laboratories and/or a list of certified laboratories on EPA’s website.

Further information is provided at

[http://water.epa.gov/lawsregs/rulesregs/sdwa/lt2/lab\\_home.cfm](http://water.epa.gov/lawsregs/rulesregs/sdwa/lt2/lab_home.cfm).

*Form Numbers:* None.

*Respondents/affected entities:* Interested States and Laboratories

*Respondent's obligation to respond:* Voluntary

*Estimated number of respondents:* 45 labs and 20 States/Territories

*Frequency of response:* Annual

*Total estimated burden:* 5,472 hours (per year). Burden is defined at 5 CFR 1320.3(b).

*Total estimated cost:* \$803,774.79 (per year), includes \$295,056.67 annualized capital or operation & maintenance (O&M) costs.

*Changes in Estimates:* There is an increase of 629 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. Changes in burden have occurred due to inflation, re-evaluation of hours for tasks, re-evaluation of O&M costs, improved demonstration of capability, and integration of laboratory oversight into existing State certification programs (State oversight of laboratories was not addressed in the currently-approved burden estimate).

The increase in the respondent universe has increased the overall burden costs for the respondents. As the States implement their certification programs, future estimates will be adjusted.

Dated: August 29, 2013.

**Ann Codrington,**

**Acting Director, Office of Ground Water and Drinking Water.**

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